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11/29/2006

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EXAMINER

KING, FELICIA C

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,658	<b>Applicant(s)</b> TERRAGNO ET AL.	
	<b>Examiner</b> FELICIA C. KING	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 21-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/29/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This Office Action is written in response to Applicants' Remarks dated 9/29/09.

#### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (Claims 1-20) in the reply filed on 9/29/09 is acknowledged. The traversal is on the grounds that the Crespo reference used in the Restriction does not disclose where the reference discloses the concentrate and that there is no burden in searching. This is not found persuasive because Crespo discloses, on pg 205-214 and specifically 206 as discussed in the previous Election Restriction, where the apparatus of Group II could be used to make a liquid concentrate as disclosed in Group II and further the liquid concentrate of Group III does not require that the material is be made by the process of claim 1 and only states that it is likely to be obtained by the process of claim 1.

2. However, Group IV will be examined with Group I due to the amendment made to claim 28.

The requirement, regarding Groups II and III, is still deemed proper and is therefore made FINAL.

#### ***Claim Objections***

3. **Claims 1, 5, 13, and 15 are objected to because of the following informalities:**

Claim 1 recites bacterial concentration "greater than  $5 \cdot 10^{10}$  ufc/ml advantageously greater than  $1 \cdot 10^{11}$  ufc/ml". Examiner has interpreted this portion of the claim as meaning "greater than  $5 \times 10^{10}$  cfu/ml advantageously greater than  $1 \times 10^{11}$  cfu/ml". Appropriate correction is required.

Claim 5 recites "greater than  $2 \cdot 10^{10}$  ufc/ml". Examiner has interpreted this portion of the claim as meaning "greater than  $2 \times 10^{10}$  cfu/ml". Appropriate correction is required.

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Claim 13 recites " $3 \cdot 10^5$  Pa". Examiner has interpreted this portion of the claim as meaning " $3 \times 10^5$  Pa". Appropriate correction is required.

Claim 15 recites "between  $0.1 \cdot 10^5$  and  $2 \cdot 10^5$  Pa and advantageously between  $0.1 \cdot 10^5$  and  $0.5 \cdot 10^5$  Pa". Examiner has interpreted this portion of the claim as meaning "between  $0.1 \times 10^5$  and  $2 \times 10^5$  Pa and advantageously between  $0.1 \times 10^5$  and  $0.5 \times 10^5$  Pa". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claim 1, the phrase "advantageously greater" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. Regarding claim 6, the phrase "and/or" renders the claim indefinite because it is considered unclear whether all of the parameters are required or whether one of the parameters is required.

8. Regarding claim 12, the phrase "advantageously between" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 1-8, 11, 12, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Applicants' NPL - Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Applicants' NPL- Journal of Applied Microbiology 2003 95, pg 146-154).**

**Regarding Claims 1-3, 6-8, 11:** Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter [pg 404, **Medium**] and where a cross flow filtration system (tangential microfiltration) is used to wash and feed bacteria with fresh medium and to concentrate the bacteria in order to get high density cultivation of bacteria where the concentration is  $1 \times 10^{11}$  cfu/ml and where the bacteria are used in yogurt drinks [pgs 404,405 **Culture**, pg 409] but does not explicitly disclose where the bacteria obtained in the fermenter are adapted and the measurement of those parameters. However, Maus discloses where Bifidobacterium are subjected to acidic pH and cold temperature conditions in order to adapt them for their application in ready to consume probiotic products [Abstract; pg. 148].

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At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa and Maus before him or her to adapt the bacteria to tolerate low temperatures and acidic pH levels because these are levels typical of dairy products and doing such would prolong the availability of the beneficial effects of bacteria like Lactobacilli and Bifidobacteria and other probiotics.

**Regarding Claim 4:** Hayakawa discloses where the medium is maintained throughout propagation at a pH of 6.5 but does not disclose where the pH is between 3 and 6 at the end of propagation. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the pH for the intended application especially where the bacteria are adapted at acidic levels, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Borsch*, 617 F.2d 272.

**Regarding Claim 5:** Hayakawa discloses where the number of cells available after growing in fermenter is  $1 \times 10^{11}$  cfu/ml (greater than  $2 \times 10^{10}$  cfu/ml).

**Regarding Claim 12:** Hayakawa discloses where the microfiltration membrane is .14 $\mu$ m [pg. 404, Bioreactor with membrane module].

**Regarding Claim 17:** Hayakawa discloses where the bacteria are revived and precultured (where the bacteria were stored at 4°C and were then precultured) [pg. 404, *Microorganisms and Culture*].

12. **Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154), as applied to claim 1 above and in further view of SCK·CEN “Physiological Approach to Monitor Space and Stress Response in Bacteria” 2003.**

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**Regarding Claim 9:** Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above and Maus discloses pH and cold stress applied to bacteria but the references do not disclose where the parameter is bacteria size. However, SCK·CEN discloses that physiological stresses such as pH can affect the size of bacteria [col. 1, Objectives].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus, and SCK·CEN before him or her to modify the method of adaptation as disclosed in Maus to include the adaptation using detection of bacteria shape as discussed in SCK·CEN as it has been disclosed that exposing bacteria to stress can cause a change in the size of the bacteria. Further this reaction (size reduction) to stress can be an indicator as to whether the bacteria would react favorably under desirable conditions.

**12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154), as applied to claim 1 above and in further view of McDaniel (US 2004/0175407).**

**Regarding Claim 10:** Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not disclose where the lengths of the bacteria are between 0.1 to 10  $\mu\text{m}$ . However, McDaniel discloses where species of Lactobacillus have lengths in the range of 1.0 -10  $\mu\text{m}$ , species of Bifidobacterium have lengths in a range of 1.5 - 8.0  $\mu\text{m}$ , species of Streptococcus have lengths in a range of 0.5 – 2.0  $\mu\text{m}$ , species of Lactococcus lengths in the range of 0.5 -1.5  $\mu\text{m}$  [pg 21, Table 3].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus, and McDaniel before him or her to include bacteria having

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lengths of between 0.1 to 10  $\mu\text{m}$  since these are physical characteristics exhibited by the preferred bacteria of the invention.

13. **Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154) as applied to claim 1 above, and in further view of van Reis (US 5,256,294).**

**Regarding Claims 13:** Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not disclose where the inlet pressure is between 0 and  $3 \times 10^5$  Pa. However, van Reis discloses where the tangential microfiltration flow has an inlet pressure of 35 or 50 psi ( $2.4 \times 10^5$  or  $3.4 \times 10^5$  Pa) [col.18, lines 51-53].

At the time of the invention it would have been obvious to one having ordinary skill in the art having the teachings of Hayakawa, Maus and van Reis before him or her to modify the filtration method of Hayakawa to include an inlet pressure of  $2.4 \times 10^5$  or  $3.4 \times 10^5$  Pa in order to better select out desired species [col.5, lines 5-15].

**Regarding Claim 15:** Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not disclose where the transmembrane pressure is between  $0.1 \times 10^5$  ( $1 \times 10^4$ ) and  $2 \times 10^5$  Pa. However, van Reis discloses where the transmembrane pressure is 5 and 10 psi ( $3.4 \times 10^4$  or  $6.8 \times 10^4$  Pa) [col. 18, lines 54-55].

At the time of the invention it would have been obvious to one having ordinary skill in the art having the teachings of Hayakawa, Maus and van Reis before him or her to modify the filtration method of Hayakawa to include a transmembrane pressure of  $3.4 \times 10^4$  or  $6.8 \times 10^4$  Pa in order to better select out desired species [col.5, lines 5-15].



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14. **Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154), as applied to claim 1 above and in further view of Carrere et al. (Applicants' NPL - Journal of Membrane Science 2001 vol. 186 219-230).**

Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not disclose where the rate of the permeate is between 0.001 and 0.1  $\text{m}^3/\text{h}/\text{m}^2$ . However, Carrere discloses permeate flux at 42 l/h/ $\text{m}^2$  (.042  $\text{m}^3/\text{h}/\text{m}^2$ ) [pg. 228 Table 4].

At the time of the invention it would have been obvious to one having ordinary skill in the art having the teachings of Hayakawa, Maus and Carrere before him or her to modify the filtration method of Hayakawa to include a permeate flux of .042  $\text{m}^3/\text{h}/\text{m}^2$  in order to obtain higher values of concentrated bacteria.

15. **Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154) as applied to claim 1 above, and in further view of Ebner et al. (US 3,974,068).**

**Regarding Claim 16:** Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not disclose a recirculation rate of 0.5  $\text{m}^3/\text{h}/\text{m}^2$  to 3.0  $\text{m}^3/\text{h}/\text{m}^2$ . However, Ebner discloses recirculation rates at .078  $\text{m}^3/\text{h}/\text{m}^2$  [col. 8, lines 63-66].

At the time of the invention it would have been obvious to one having ordinary skill in the art having the teachings of Hayakawa, Maus and Carrere before him or her to modify the filtration method of Hayakawa to include recirculation rate in order to increase filter efficiency. Although,

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Ebner does not disclose the same recirculation range as disclosed in the instant claim, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the recirculation rate based upon the size and concentration of bacteria and amount of medium used which would influence the rate of recirculation and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

16. **Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154) as applied to claim 1 above and in further view of Bensel (US 2,364,049).**

**Regarding Claims 18 and 19:** Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not disclose where the liquid concentrate is packaged in flexible and hermetic bags and where the liquid concentrate in the bags are kept at temperatures of -50° C to 4°C. However, Bensel discloses packaging perishable items by sterilizing them and loading into flexible heat sealable bags that are impervious to air and moisture (hermetic) [pg. 2, 1<sup>st</sup> col. lines 53-58] and where the bags are kept at temperatures lower than -10°C [pg. 2, 2<sup>nd</sup> col. lines 38-41].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus and Bensel before him or her to package the liquid concentrate in flexible hermetically sealed, sterile packaging at low temperatures because it would prevent the degradation of the liquid concentrate (maintain the shelf life) and prevent contamination with undesirable pathogenic bacteria or bacteria that has not been adapted for use as probiotics.

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**17. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154) and Bensel (US 2,364,049), as applied to claim 19 above and in further view of Rinfret et al. (US 3,228,838).**

**Regarding Claim 20:** Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not explicitly disclose reheating to a temperature between 25°C and 45°C. However, Rinfret discloses preserving biological substances such as blood, bacteria, yeast, beverages from degradation by freezing and then thawing at 37 °C [col. 1, lines 16-20; col. 7, lines 13-37].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus, Bensel, and Rinfret before him or her to thaw the bacteria at 37 °C because it would bring the bacteria to a temperature that is favorable to maintaining their viability [Rinfret, col. 3, lines 16-19].

**18. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154) as applied to claim 1 above and in further view of Bengtsson-Riveros et al. (US 2004/0115308).**

**Regarding Claim 28:** Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not explicitly disclose where the bacteria are added to a food product at the end of a production line. However, Bengtsson-Riveros discloses where the bacteria can be directly added to the consumable product and stored with the consumable product [pg. 2, para 0024] and further discloses adding probiotics to the consumable product before packaging the product [pg. 3, para 0040].

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At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus, and Bengtsson-Riveros before him or her to include the addition of the bacteria after the food is produced and before packaging in order to further ensure that the bacteria is exposed to temperatures at which the food will be stored, which will further help the bacteria maintain its viability and help maintain the overall shelf stability of the food product.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 2, 6-9, 18, 19, 20, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8-10, 12, 15, 16, 19 and 22 of copending Application No. 10/509507. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed toward adapted liquid bacterial concentrates that are treated by tangential microfiltration; where the bacteria are *Lactobaccilli*, *Bifidobacterium*, *Streptococcus*, or *Lactococcus*; where the parameters are measured by the medium

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or bacteria; where the bacteria is added at the end of a production line and packaged in flexible hermetically sealed bags and can be reheated after packaging.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FELICIA C. KING whose telephone number is (571)270-3733. The examiner can normally be reached on Mon- Thu 7:30 a.m.- 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m. alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/F. K./  
Examiner, Art Unit 1794

/Jennifer McNeil/  
Supervisory Patent Examiner, Art Unit 1794